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In re Application of : Eberhard Nieschlag et al.

Serial No.: 09/764,149

Group Art Unit: 1615

Filed: January 19, 2001

Examiner:
Rachel M. Bennett

For: MALE CONTRACEPTIVE FORMULATION COMPRISING NORETHISTERONE

SUPPLEMENTAL AMENDMENT

Assistant Commissioner for Patents
Washington, D. C. 20231

Sir:

Supplemental to the Amendment filed May 21, 2002, kindly amend the above-identified application as follows.

IN THE SPECIFICATION

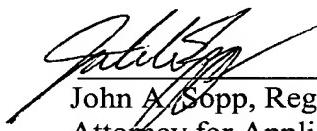
Replace page 20, in its entirety, with the attached new page 20. A marked up version is not supplied since no changes are made to the page, it is merely being replaced by a more legible copy.

REMARKS

A substitute, more legible, page 20 is being submitted per the Examiner's request in the Office Action of December 21, 2002.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



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FILED: May 28, 2002

1.1.1 Study flow chart

	Screening	Start	Treatment												Observation				
			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
Visit			A	B ¹	day 0 ²	W2 ³	W4	W6	W8	W12	W16	W18	W20	W24	W28	W36	W44	W56	
Assessment																			
Group A																			
NET-Et administration (mg)						200			200		200		200						
TU administration (mg)							1000		1000		1000		1000						
Group B																			
NET-Et administration (mg)								400		400		400		400					
TU administration (mg)									1000		1000		1000						
Group C																			
NET-A administration (mg)										10 mg		daily							
Dispensation of vials										V12									
TU administration (mg)											1000								
Informed Consent/Demographics	ABC																		
Check of Inclusion/Exclusion	ABC		ABC																
Randomization/Diary dispensed			ABC																
Medical/androl/medication history	ABC	ABC	ABC																
Vital signs	ABC	ABC	ABC																
Physical examination	ABC			ABC															
Andrological examination	ABC			ABC															
Semen analysis	ABC	ABC		ABC															
General laboratory	ABC																		
Hormones	ABC	ABC		A		ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	
Exam/Ultrasoundography of prostate		ABC																	
Ultrasoundography of testes		ABC																	
Return of diary/vials, if available						C	C	C	C	C	C	C	C	C	C	C	C	C	
AEs/concomitant medication						A	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	
Questionnaire	ABC	ABC				ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	

Table 1

¹ At least 7 days after visit 1² Not more than 8 weeks after visit 1³ A deviation of ± 5 days will be tolerated